

### REMARKS

The above amendments have been provided based on the format described at 1265 Off. Gaz. Pat. Office 87 (December 17, 2002) and as authorized by Deputy Commissioner for Patents, Stephen Kunin on January 31, 2003.

Claims 6 and 23-30 were pending, all of the claims were rejected in the previous Office action, and no claims were allowed. Claims 6 and 30 have been amended in light of business-related reasons and not in acquiescence to any rejection made by the Office. Support for the amendment to claims 6 and 30 can be found in the specification at page 8, lines 29-36 and page 29, line 36 to page 30, line 2. It is believed that no new matter has been added.

Claims 6 and 23-30 are currently pending. Although this amendment is proposed after a final rejection, it is respectfully submitted that entry advances prosecution by placing the claims in a better position for allowance and appeal.

#### Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 30 is rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to be sufficiently described in the specification as filed. According to the Examiner, there is no support for the kit of claim 30. Applicants respectfully traverse this rejection.

Claim 30 is not limited to a separate solid phase for immobilizing the protein. The instant specification expressly discloses a kit comprising *inter alia* a solid phase for immobilizing the claimed protein. *See, e.g.*, the specification, at page 47, lines 8-16, and at page 49, lines 4-15. Contrary to the assertions in the Action, this language in the specification does not require the solid phase to be a separate component. The Office is reading a limitation into the disclosure that does not exist. A kit containing the labeled antibody, the unlabeled protein, and a solid phase for immobilizing the protein has the same essential elements as a kit containing a labeled antibody and a pre-immobilized, unlabeled protein on a solid support - the patentably novel protein, its patentably novel specific antibody, and a means for immobilizing the patentably novel protein. Moreover, Applicants point out that the specification expressly

discloses kits using the claimed protein pre-bound to a solid support at page 44, line 26 to page 45, line 2 and at page 47, line 5-7 (stating that the “312C2 can be immobilized on various matrixes”).

Claim 30 is not limited to kits containing compartments. The specification does not limit kits to those with compartments containing reagents and instructions for use. The compartments containing reagents and instructions are disclosed as “normally ... provided.” *See* specification, at page 47, lines 14-16. In other words, one embodiment of the disclosed kits contains such compartments as optional additional elements of the claimed invention.

Hence, Applicants submit that the specification clearly conveys to a skilled artisan the possession of a kit comprising a labeled antibody, an unlabeled protein immobilized to a solid support, and the instruction for use, in the specification as filed. Compartments are disclosed only as optional elements of the claimed kit.

In light of the above remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph is overcome. Therefore, Applicants request the withdrawal of this rejection.

#### **Rejection Under 35 U.S.C. § 102(e)**

Claims 6 and 26 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated in view of Baum *et al.* (U.S. Patent No. 5,457,035). The Examiner asserts that the specification does not define what “specifically binds a protein” means or encompasses. According to the Examiner, the disclosed definition does not state that the epitope is only found in a protein/peptide of SEQ ID NO:2 or 4. Therefore, the Examiner asserts that antibodies that bind amino acids 139-143 of OX40-L would bind the same sequence in SEQ ID NO:4. Applicants respectfully traverse this rejection.

Applicants submit that the definition of antibody specificity disclosed in the specification is sufficiently definite for one of skill in the art. The meaning of the term “specific” is unchanged in the art or elsewhere. Furthermore, there is no requirement that the definition of

specificity for an antibody make explicit reference to the epitopes within the protein or peptide of SEQ ID NO:2 or 4. A skilled artisan would recognize that the epitopes of interest are those within the claimed protein or peptide. If the Examiner is aware of a novel definition of a specific antibody accepted in those of skill in the art, Applicants respectfully request that the Examiner support this rejection with those facts in an affidavit by the Examiner according to MPEP § 2144.03. According to MPEP § 2144.03,

When a rejection is based on facts within the personal knowledge of the examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner.

Moreover, SEQ ID NO:4 is a novel sequence distinct from the OX40-L sequence of Baum. The antibody or antigen binding fragment as claimed herein specifically binds at least 8 amino acids of SEQ ID NO:2 or 4 and thus is not anticipated by an antibody specifically binding the five amino acid sequence of OX40-L in Baum as cited by the Office.

In light of the above remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 102(e) is overcome. Applicants request the withdrawal of this rejection.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 6 and 23-29 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baum *et al.* (U.S. Patent No. 5,457,035) in view of Godowski *et al.* (U.S. Patent No. 5,709,858). According to the Action, the claimed invention is *prima facie* obvious because Baum teaches monoclonal antibodies that bind SEQ ID NO:4 and Godowski teaches antibody fragments, humanized antibodies, labeled antibodies, and immobilized antibodies. Applicants respectfully traverse this rejection.

**1. The combination of Baum and Godowski does not result in the claimed invention.**

Baum does not teach SEQ ID NO:4 and therefore does not teach antibodies that bind SEQ ID NO:4. The Examiner appears to rely on a five amino acid sequence of asserted homology in contending that Baum teaches SEQ ID NO:4. SEQ ID NO:4 is 241 amino acids in length. The five amino acid region of asserted homology does not teach the remaining 236 amino acids in SEQ ID NO:4 or antibodies specific for sequences of at least 8 amino acids within SEQ ID NO:4.

Godowski fails not remedy this deficiency in Baum. Godowski discloses novel receptor protein kinases and the generation of antibodies specific for the disclosed kinases. These protein kinases are completely unrelated to OX40-L. Therefore, the combination of Godowski with Baum does not result in the claimed invention because neither teaches SEQ ID NO:4 nor antibodies specific for SEQ ID NO:4.

**2. Neither Baum nor Godowski provide a motivation to combine the references or a reasonable expectation of success for such a combination.**

Baum and Godowski are directed to unrelated inventions with no disclosure that directs a skilled artisan to extend their teachings to any other invention. Therefore, there is no motivation to combine these references. Furthermore, the references do not provide a reasonable expectation of success. As the references do not even address SEQ ID NO:4, it is impossible for them to convey any expectation of success regarding antibodies specific for the claimed sequence.

In sum, Applicants respectfully submit that a combination of references cannot make obvious an invention that is neither taught nor suggested in the references.

In light of the above remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 103(a) is overcome and request the withdrawal of this rejection.

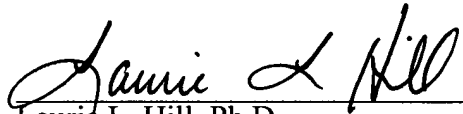
### CONCLUSION

Applicants submit that the rejections under 35 U.S.C. §§ 112, 102, and 103 have been overcome by the above remarks. Early allowance of pending claims 6 and 23-30 is respectfully requested. In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000510.

Respectfully submitted,

Dated: April 16, 2003

By:

  
Laurie L. Hill, Ph.D.  
Registration No. 51,804

Morrison & Foerster <sup>LLP</sup>  
3811 Valley Centre Drive  
Suite 500  
San Diego, California 92130-2332  
Telephone: (858) 720-7955  
Facsimile: (858) 720-5125